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scheme to the 'restricted account period,' Relator would have been able, as alleged in her detailed Complaint, to present testimony and admissible evidence concerning the "Kickback" scheme regarding hundreds of accounts serviced by Duxbury's colleague, Dean McClellan, whose personal knowledge and documents were contemporaneous to Duxbury and continued through 2004. With this proof, Relator would have been able to demonstrate the triable nature of the multi-year nationwide scheme regardless of Ortho's ability to produce additional evidence regarding the scheme. Under these circumstances, the granting of summary judgment would improperly deprive Relator of her civil right to prosecute this action and obtain a substantial recovery on behalf of the United States through a "productive private enforcement" of the False Claims Act.

II. RELEVANT PROCEDURAL AND FACTUAL HISTORY

This Court in granting Ortho's motion to dismiss the claim that Ortho had engaged in a multi-year nationwide "Kickback" scheme ruled that the "Public Disclosure" bar, 31 USC 3730(e)(4)(A), applied to Relator's "Kickback claim."¹ This Court adopted Ortho's assertion that the "*essential facts* supporting" the "claim" had been "publicly disclosed" in the AWP MDL litigation.² This Court also adopted Ortho's assertion that Dean McClellan's "Kickback claim" was barred under the "First to File" bar, USC 3730(b)(5), because it was "based on *essentially the same facts* that Relator Duxbury already asserted".³

¹ *US ex rel. Duxbury v. Ortho Biotech Products LP*, 551 F. Supp 2d 100, 108 (USDC DMa 2008).

² *Id.* at 108; See also, 1-17-07 Ortho's Memorandum in support of its motion to dismiss at 8.

³ *Id.* at 109; See also, 1-17-07 Ortho's Memorandum in support of its motion to dismiss at 20 (emphasis added).

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In ruling in Ortho's favor on these points, this Court analyzed in detail the allegations made by Duxbury and McClellan in the Amended complaint regarding the "Kickback claim" and the public disclosure of the AWP MDL allegations in the Master Consolidated Class Action Complaint (MCC). The Court noted that in the 10-6-06 1st Amended Complaint by Mark Duxbury and Dean McClellan, the following was alleged about the "Kickback scheme":

Relators allege that beginning in 1992, *[Ortho] undertook a scheme to give kickbacks to providers and hospitals to induce them to prescribe Procrit*. The kickbacks allegedly included free samples, off-invoice discounts, rebates, consulting fees, educational grants, payments to participate in studies or trials and advisory board honoraria. Relators allege that the kickbacks caused providers and hospitals to submit false claims for payment to Medicare. *They claim the time period of the false claims is from December 1992 to the present.*

US ex rel. Duxbury v. Ortho Biotech Products LP, 551 F. Supp 2d 100, 104 (USDC DMA 2008)(emphasis added).

This Court compared the Complaint allegations made by Duxbury and McClellan to the following AWP MDL allegations in the MCC:

The MCC alleged that *[Ortho] ... engaged in widespread fraudulent conduct*, including kickbacks, improper use of free samples, discounts, rebates and other hidden and improper inducements and price reductions.

US ex rel. Duxbury v. Ortho Biotech Products LP, 551 F. Supp 2d 100, 106 (USDC DMA 2008)(emphasis added).

This Court concluded Duxbury's and McClellan's "Kickback allegations [of a "*scheme to give kickbacks to providers and hospitals to induce them to prescribe Procrit ... from December 1992 to the present*"]⁴ are the same as those alleged in the MCC,"⁵ ie Ortho "engaged in

⁴ *US ex rel. Duxbury v. Ortho Biotech Products LP*, 551 F. Supp 2d 100, 104 (USDC DMA 2008)

⁵ *Id.* at 108 (emphasis added).

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widespread fraudulent conduct” regarding “Kickbacks”.⁶ As a result, this Court ruled the “Public Disclosure Bar” was triggered.⁷ Because the Court found that the “Kickback claim” allegations were the “*same*” in both the Amended Complaint and MCC, the Court had to determine whether Duxbury had “direct and independent knowledge” of the information underlying the “Kickback claim” in order to determine if Duxbury qualified under the “Original Source” exception (USC 3730(e)(4)(B)) to the “Public Disclosure” bar (USC 3730(e)(4)(B)). The Court found that Mark Duxbury’s employment as a Product and Account Specialist provided Duxbury with “knowledge of the alleged fraud” that was “both *independent* and *direct*”. The Court found as follows:

In his position as a Product Specialist and later Regional Key Account Specialist for [Ortho’s] Western Division Oncology sales force, Duxbury was responsible for the promotion and sale of Procrit in the western United States. The complaint alleges that, at [Ortho’s] direction, he gave providers free samples of Procrit and instructed the providers to submit Medicare claims for the samples, ... and directly provided discounts, rebates, educational grants, and other off-invoice discounts to providers to lower the actual acquisition cost of Procrit. ... *His knowledge of the alleged fraud is both independent and direct.*

US ex rel. Duxbury v. Ortho Biotech Products LP, 551 F. Supp 2d 100, 109 (USDC DMa 2008).

This Court ruled further that McClellan “*does not assert any new claims* of his own, but *only adds additional supporting facts to the legal claims previously made*” by Duxbury.⁸ This Court ruled therefore that McClellan had to show that he had provided his information to the Government prior to the Duxbury suit first being filed.⁹ This Court ruled that McClellan had not

⁶ Id. at 108 (emphasis added).

⁷ Id. at 108.

⁸ Id. at 109 (emphasis added).

⁹ Id. at 109.

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sufficiently pleaded facts that he had provided his information to the Government before the original action was filed.¹⁰ In addition, the Court agreed with Ortho that “even if [McClellan] qualified ...[he] would be barred by the “first-to-file” bar.”¹¹ This Court stated, “as discussed more fully *infra*, the first-to-file bar in §3730(b)(5) prevents private plaintiffs ‘from bringing *related* actions based on the *same underlying facts*’.”¹² This Court elaborated on the ‘first-to-file’ bar. It stated “the majority of courts interpret §3730(b)(5) to bar a later allegation which states *all the essential facts of a previously-filed claim*, even if the later claim incorporates somewhat different details.”¹³ This Court recognized that “the common principle is that section §3730(b)(5) precludes a subsequent relator’s claim that alleges the defendant engaged in the *same type of wrongdoing* as that claimed in a prior action even if the allegations cover a different time period or location within a company”.¹⁴

Although this Court ruled that Duxbury satisfied the requirements of the “Original Source” exception (USC 3730(e)(4)(B)) to the “Public Disclosure” bar (31 USC 3730(e)(4)(A)), nevertheless, this Court dismissed Relator’s “Kickback” claim. This Court did so based on its ruling that Relator had not passed muster under FRCP Rule 9(b) because, according to this Court, Relator had not pled with sufficient particularity the allegation that the scheme resulted in

¹⁰ Id. at 110.

¹¹ Id. at 110.

¹² Id. at 110 (emphasis added).

¹³ Id. at 111 (emphasis added).

¹⁴ Id. at 111 (emphasis added).

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the "actual" submission of false claims ("[Relator] fails to identify a single false claim consequently filed by these providers").¹⁵

On August 12, 2009, the United States Court of Appeals for the First Circuit issued an opinion affirming this Court's January 28, 2008, decision in part and reversing the decision in part. The 1st Circuit ruled that Mark Duxbury had pled his "Kickback" claim (Count I) with sufficient particularity under Federal Rule of Civil Procedure 9(b) and remanded the "Kickback" claim back to the District Court. In its opinion, the 1st Circuit extolled the purpose of the False Claims Act to encourage "productive private enforcement."¹⁶ The court ruled that "Duxbury's allegations pass muster for purposes of Rule 9(b)" and that "Duxbury has alleged facts that false claims were in fact filed by the medical providers he identified, *which further supports a strong inference that such claims were also filed nationwide.*"¹⁷

On "October 13, 2009 Relator Plaintiff Mark Duxbury died."¹⁸ On December 10, 2009, the administrator of Relator Mark Duxbury's estate, Chinyelu Duxbury, Mark Duxbury's surviving spouse, was substituted for him as Relator in this action.¹⁹

Over Relator's Opposition,²⁰ this Court, based on Ortho's 12-31-09 "Brief,"²¹ entered its 9-

¹⁵ *US ex rel. Duxbury v. Ortho Biotech Products LP*, 551 F. Supp 2d 100, 115 (USDC DMA 2008).

¹⁶ *US ex rel Duxbury v. Ortho Biotech Products LP*, 579 F3d 13, 27 (1st Cir. 2009).

¹⁷ *US ex rel Duxbury v. Ortho Biotech Products LP*, 579 F3d 13, 32 (1st Cir. 2009) (emphasis added).

¹⁸ 11-11-09 Relator's "Statement Noting Death."

¹⁹ Order dated December 10, 2009 (Dkt. 106).

²⁰ 1-18-10 "Relator Duxbury's Opposition to Ortho's 12-31-09 'Brief'."

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27-10 Order limiting, temporally and geographically, discovery and recovery regarding Relator's "Kickback" scheme claim. Pursuant to this Court's 9-27-10 ruling that this Court "lacks Jurisdiction" over the multi-year nationwide scheme alleged by Relator, discovery and recovery was limited to the last eight months of Duxbury's employment (November 6, 1997 – July 20, 1998) and the five accounts²² during that period over which Duxbury had "direct and independent knowledge."²³

On February 3, 2011, this Court denied Relator's 12-30-10 motion for leave to appeal the Court's September 27, 2010 ruling.²⁴

On July 1, 2011, Defendant filed an Answer to the Complaint denying that any of the remaining claims, as limited by the Court's September 27, 2010, ruling, had merit.²⁵

On June 13, 2011, Relator and Defendant filed a Local Rule 16.1(d) Joint Statement ("Joint Statement") that, consistent with the Court's September 27, 2010, ruling, limited discovery to Duxbury's Count I claims from (i) the November 6, 1997 to July 20, 1998 time period and (ii) the following five accounts: St. Joseph's Hospital in Tacoma, Washington; Rainier Oncology of Puyallup, Washington; Western Washington Cancer Treatment Center in Olympia, Washington;

²¹ 12-31-09 Ortho's "Brief On The Proper Scope Of Relator's Remaining Kickback Claims." This Court treated Ortho's 12-31-09 "Brief" as a motion. See, 12-10-09 Docket Entry.

²² St. Joseph's Hospital in Tacoma, Washington; Rainier Oncology of Puyallup, Washington; Western Washington Cancer Treatment Center in Olympia, Washington; Memorial Clinic in Olympia, Washington; and Memorial Clinical Oncology Group in Washington. See 10-31-11 Stipulation at Ex. A par. 3, 6 to Ortho's 11-15-11 Motion for Summary Judgment.

²³ 9-27-10 Memorandum of Decision p. 5-6.

²⁴ 10-31-11 Stipulation at Ex. A par. 4 to Ortho's 11-15-11 Motion for Summary Judgment; Elec. Order dated Feb. 3, 2011.

²⁵ 10-31-11 Stipulation at Ex. A par. 5 to Ortho's 11-15-11 Motion for Summary Judgment.

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Memorial Clinic in Olympia, Washington; and Memorial Clinical Oncology Group in Washington.²⁶ The Court endorsed the Joint Statement in its entirety on June 22, 2011.²⁷

Pursuant to the schedule, both parties timely served interrogatories and requests for production of documents, made reasonable efforts to provide responses, and during the discovery period conferred and cooperated with each other in good faith.²⁸

At the conclusion of the discovery period, in response to Defendant's discovery requests, Relator informed Defendant that Relator had not identified and does not possess any documents, witness testimony, or other admissible evidence to support Relator's remaining allegations, as limited by the Court's Order dated September 27, 2010, namely identification of a specific payment that could be considered a "kickback" made to the accounts serviced by Mark Duxbury during November 6, 1997 to July 20, 1998 as set forth in paragraph 6 of the 10-31-11 Stipulation. Similarly, Defendant informed Relator that it had not uncovered any such materials as well. The Parties thus agreed that each had its opportunity to discover any specific payments that could be considered "kickbacks" made to the accounts serviced by Mark Duxbury during November 6, 1997 to July 20, 1998, and that such discovery was now complete.²⁹

In light of the acknowledgment by Relator contained in Paragraph 10 of the 10-31-11 Stipulation, Relator and Defendant agreed to enter into the 10-31-11 Stipulation in the interest of

²⁶ Id. par. 6.

²⁷ Id. par. 8.

²⁸ Id. par. 9.

²⁹ 10-31-11 Stipulation at Ex. A par. 10 to Ortho's 11-15-11 Motion for Summary Judgment.

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the efficient administration of this matter.³⁰

Based on the acknowledgment contained in paragraph 10 of the 10-31-11 Stipulation and the Court's September 27, 2010 Order and the limitations described in the 10-31-11 Stipulation, neither Defendant's summary judgment motion, nor Relator's opposition thereto, have attached any documents, witness testimony, or any other admissible evidence beyond the Stipulation.³¹

III. REASONS WHY SUMMARY JUDGMENT SHOULD BE DENIED

Ortho's summary judgment motion should be denied because Relator has been deprived of a full and fair opportunity to prosecute this action. The False Claims Act provides that "a person may bring a civil action for a violation" of the act "for the United States Government." 31 USC §3730(b). "If the Government elects not to proceed with the action, the person who initiated the action *shall have the right to conduct the action.*" 31 USC §3730(c)(3)(emphasis added). The Court's 9-27-10 Order restricting discovery and recovery to the 'restricted account period' improperly denied Relator her "*right to conduct the action.*"

Relator in her 1-18-10 Opposition and 12-30-10 Request for permission to appeal the 9-27-10 Order detailed the reasons why restricting discovery and recovery to the 'restricted account period' was in fundamental derogation of the clear words, purpose and intent of the False Claims Act, 31 USC §3730 and contrary to: the the Supreme Court's decision in *Rockwell Internt'l. Corp. v. US*, 549 457 (2007); the 1st Circuit's decision in *US ex rel Duxbury v. Ortho Biotech Prod. LP*, 579 F.3d 13 (1st Cir. 2009); this Court's rulings in *US ex rel Duxbury v. Ortho Biotech Prod. LP*, 551 F. Supp 2d 100 (USDC DMa 2008); and the precedents set in other

³⁰ Id. par. 11.

³¹ Id. par. 11.

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jurisdictions including, *US ex rel Walker v. R&F Prop. Of Lake County*, 433 F.3d 1349, 1359 (11th Cir. 2005)³². Relator refers to the arguments made in its prior filings regarding this authority.

The Court's 9-27-10 Order restricting Relator's discovery and recovery has artificially and improperly prevented Relator from presenting admissible evidence in support of her "Kickback" claim that Ortho engaged in a multi-year nationwide scheme to defraud Medicare. The Court's restriction coupled with Mark Duxbury's untimely death has improperly prevented Relator from demonstrating through the testimony of Dean McClellan and the thousands of documents in his possession the triable nature of Relator's claim. Had this Court not imposed the restriction on the discovery and recovery available in this matter, Relator would have been able to undertake "productive private enforcement" of the False Claims Act to the benefit of US Taxpayers who are alleged to have sustained several billion dollars of fraudulent Medicare reimbursement claims.

The Relator has been established as the original whistle blower regarding Ortho's multi-year nationwide "Kickback" scheme. Relator has the testimony and documents to prove a cross section of claims representative of the widespread scheme. Mark Duxbury's untimely death has deprived Relator of the means to prove the scheme resulted in the use of "kickbacks" to induce

³² In *US ex rel Walker v. R&F Prop. Of Lake County*, 433 F.3d 1349, 1359 (11th Cir. 2005) the court overturned the District Court's ruling restricting discovery to the period of the Relator's employment. In doing so, the 11th Circuit ruled that if the Complaint "alleges an ongoing practice of false" claim submission that is "not limit[ed] ... to the time period during which [Relator] was employed by [Defendant]" then the "proper temporal range for discovery is" the dates alleged in the Complaint. The 11th Circuit noted that "Under the False Claims Act, any person may serve as a *qui tam* relator ... the relator need not have any relation at all to the defendant" and the "United States is the real party in interest in a *qui tam* action under the FCA, even if it is not controlling the litigation." Relator is not aware of any case, other than this Court's 9-27-10 decision, that has ruled otherwise.

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the submission of fraudulent claims during the 'restricted account period.' Under these circumstances, it would be fundamentally unjust to enter summary judgment against Relator on a claim that Relator can demonstrate is triable if not for the Court's 9-27-10 restrictions.

For these reasons, Relator respectfully requests the Court deny Ortho's motion for summary judgment and allow Relator to undertake "productive private enforcement" of the "Kickback" claim.

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Respectfully submitted by counsel for Relator:

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CERTIFICATE OF ELECTRONIC SERVICE

This is to certify that on the 6th day of December, 2011 the above document was served on Ortho and the United States by electronic service.

/s/ Jan Schlichtmann
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Attorney for Relator